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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,099

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Richard O. Chen

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EXAMINER

RIGGS II, LARRY D

ART UNIT

PAPER NUMBER

1631

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/632,099	Applicant(s) CHEN ET AL.	
	Examiner LARRY D. RIGGS II	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-9, 13, 14 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9, 13, 14 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/20/2009 and 05/07/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments filed 27 February 2009 are acknowledged and entered.

Status of Claims

Claims 6, 10-12, 15-57 and 59-61 are cancelled. Claims 1-5, 7-9, 13, 14 and 58 are currently pending and under consideration.

Information Disclosure Statement

The information disclosure statements filed 20 March 2009 and 07 May 2009 are acknowledged. Signed copies of the corresponding 1449 forms have been included with this Office action.

Priority

Applicant's claim for the benefit of a prior-filed application 60/353,176 filed February 4, 2002 under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged and accepted.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Withdrawn Rejections/Objections

The objection of the Oath/Declaration in the Office action mailed 18 September 2008 is withdrawn in view of the amendments filed 27 February 2009.

The rejection of claims 1-5, 7-9, 13, 14 and 58 under 35 U.S.C. 101, in the Office action mailed 18 September 2008 is withdrawn in view of the amendments filed 27 February 2009.

The rejection of claims 1-5, 7-9, 13, 14 and 58 under 35 U.S.C. 102(a) over Qu et al., in the Office action mailed 18 September 2008 is withdrawn in view of the amendments filed 27 February 2009.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The instant rejection is newly applied.

Claims 1-5, 7-9, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "querying the database to identify a disease-related" in line 1 of step b). The metes and bounds of the limitation are unclear. Step a) of the instant claims provides a database that encompasses "stored genomic information", line 3 of step a). However one skilled in the art would be unclear what is to be identified that is disease-related within the database.

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Claims 2-5, 7-9, 13 and 14 depend from claim 1.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The instant rejection is newly applied.

Claims 1-5, 7-9, 13, 14 and 58 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to a method of identifying a drug discovery target. The instant claims are drawn to the abstract process steps of providing a computer for storing and accessing genomics information, querying the database, identifying the biological objects and processes that act on those objects in the disease related pathway, displaying the drug discovery target to a user.

The Supreme Court has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself. A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. See *in re Bilski* 88 USPQ2d 1385 (Fed. Cir. 2008) and *in re Comiskey* 89 USPQ2d 1655 (Fed. Cir. 2009). See also *Benson*, 409 U.S. at

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70; Diehr, 450 U.S. at 192; see also Flook, 437 U.S. at 589 n.9; Cochrane v. Deener, 94 U.S. 780, 788 (1876).

The instant claims do not recite or inherently involve any transformation of an article, therefore the Examiner must determine if the instant claims have a tie to a particular machine or apparatus. The instant claims do not recite any limitation that ties the recited abstract process to any particular machine or apparatus. Storing and accessing genomics information within a database in a computing device is not a tie to a particular machine or apparatus but is insignificant extra-solution activity. Likewise, displaying the drug discovery target is an insignificant extra-solution activity. Neither the storing of data nor displaying of data is critical to the invention of selecting a drug discovery target, for storing and displaying only preempt the noted abstract process. Nominal or token recitations will not suffice, E.g. displaying, inputting, obtaining, See *Ex parte Langemyr* (May 28, 2008). Applicants are cautioned against introduction of new matter in an amendment.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The instant rejection is newly applied with new art of record.

Claims 1-5, 7-9, 13, 14 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Hughes et al. (Cell, 2000, 102, 109-126).

The instant claims provide a method for identifying a drug discovery target by providing a computer database for storing and accessing genomic

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information, querying the database to identify a disease related pathway, identifying biological objects and processes that act on the objects in the disease-related pathway, displaying the drug discovery target.

Regarding claim 1, Hughes et al. shows the monitoring of hundreds of cellular components with the construction of a database (compendium) of expression profiles from mutation and chemical treatment within *S. cerevisiae*, (abstract; page 124, left column, first full paragraph; figures 1-3; table 3). Hughes shows that cellular transcriptional response to different steps within a pathway and determine the effects of disease on the pathway, (page 109, right column, last paragraph; page 118, right column). Hughes components of cellular pathways as a novel targets of the drug dycyclonine, (abstract, page 115, right column; page 123, left column).

Regarding claim 2, Hughes shows the use of a 2-color cDNA hybridization assay to produce 300 expression profiles, (page 111, left column, last paragraph - right column, first paragraph; page 124, right column, second paragraph; Figure 1).

Regarding claims 3-5, Hughes shows the database was proprietary when produced but now is available to the public, (page 124, left column, second and third paragraphs).

Regarding claims 7 and 8, the specification defines slots and facets as to define and structure the taxonomic relationship between classes or groups of things that share similar properties, (see specification, page 9, paragraphs 40 and 41). Hughes shows clustering analysis wherein profiles and transcripts were

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selected from a data matrix, and experiments and responsive genes were grouped by agglomerative hierarchical clustering, where the similarity measurement is the error-weighted correlation coefficient (page 124, third paragraph). Hughes shows genes and experiments were re-ordered according to the resulting clustering similarity trees and the significance (p value) for gene regulation takes the gene measurement error and biological variation in control into account, (page 124, third paragraph; Table 3).

Regarding claim 9, Hughes shows that a compendium may be used to discover unanticipated activities of drugs and ensure that only desired treatment effects are occurring in patients, (page 124, left column, first full paragraph).

Regarding claim 13, Hughes shows expression profiles of genes of both mutant and controls of *S. cerevisiae*.

Regarding claim 14, Hughes shows multiple steps of the same pathway from the 300 expression profiles and relational database, (abstract, page 109, right column; Table 3).

Regarding claims 58, Hughes et al. shows the monitoring of hundreds of cellular components with the construction of a database (compendium) of expression profiles from mutation and chemical treatment within *S. cerevisiae*, (abstract; page 124, left column, first full paragraph; figures 1-3; table 3).

Hughes shows that cellular transcriptional response to different steps within a pathway and determine the effects of disease on the pathway, (page 109, right column, last paragraph; page 118, right column). Hughes shows clustering analysis wherein profiles and transcripts were selected from a data matrix, and

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experiments and responsive genes were grouped by agglomerative hierarchical clustering, (page 124, third paragraph). Hughes components of cellular pathways as a novel targets of the drug dycyclonine, (abstract, page 115, right column; page 123, left column).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is (571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIC S. DEJONG/
Examiner, Art Unit 1631

/LDR/
Larry Riggs
Examiner, Art Unit 1631